

Package leaflet: Information for the user

Cinacalcet 30 mg film-coated tablets

Cinacalcet 60mg film-coated tablets

Cinacalcet 90mg film-coated tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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2. What you need to know before you take Cinacalcet film-coated tablets
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1. What Cinacalcet film-coated tablets are and what they are used for

Cinacalcet film-coated tablets work by controlling the levels of parathyroid hormone (PTH), calcium and phosphorous in your body. It is used to treat problems with organs called parathyroid glands. The parathyroids are four small glands in the neck, near the thyroid gland, that produce parathyroid hormone (PTH).

This medicine is used in adults:

- to treat secondary hyperparathyroidism in patients with serious kidney disease who need dialysis to clear their blood of waste products
- to reduce high levels of calcium in the blood (hypercalcaemia) in patients with parathyroid cancer
- to reduce high levels of calcium in the blood (hypercalcaemia) in patients with primary hyperparathyroidism when removal of the gland is not possible

Cinacalcet is used in children aged 3 years to less than 18 years of age:

- to treat secondary hyperparathyroidism in patients with serious kidney disease who need dialysis to clear their blood of waste products, whose condition is not controlled with other treatments

In primary and secondary hyperparathyroidism too much PTH is produced by the parathyroid glands. "Primary" means that the hyperparathyroidism is not caused by any other condition and "secondary" means that the hyperparathyroidism is caused by another condition, e.g., kidney disease. Both primary and secondary hyperparathyroidism can cause the loss of calcium in the bones, which can lead to bone pain and fractures, problems with blood and heart vessels, kidney stones, mental illness and coma.

2. What you need to know before you take Cinacalcet film-coated tablets

DO NOT take Cinacalcet film-coated tablets:

- if you are allergic to cinacalcet or any of the other ingredients of this medicine (listed in section 6)
- if you have low levels of calcium in your blood. Your doctor will monitor your blood calcium levels

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Cinacalcet film-coated tablets.

Before you start taking this medicine, tell your doctor if you have or have ever had:

- **seizures** (fits or convulsions). The risk of having seizures is higher if you have had them before
- **liver problems**
- **heart failure**

Cinacalcet film-coated tablets reduce calcium levels. Life threatening events and fatal outcomes associated with low calcium levels (hypocalcaemia) have been reported in adults and children treated with cinacalcet.

Please tell your doctor if you experience any of the following which may be signs of low calcium levels: spasms, twitches, or cramps in your muscles, or numbness or tingling in your fingers, toes or around your mouth or seizures, confusion or loss of consciousness while being treated with this medicine.

Low calcium levels can have an effect on your heart rhythm. Tell your doctor if you experience an unusually fast or pounding heartbeat, if you have heart rhythm problems, or if you take medicines known to cause heart rhythm problems, while taking this medicine.

For additional information see section 4.

During treatment with this medicine, tell your doctor:

- if you start or stop smoking, as this may affect the way Cinacalcet film-coated tablets work

Children and adolescents

Children under the age of 18 with parathyroid cancer or primary hyperparathyroidism must not take Cinacalcet film-coated tablets.

If you are being treated for secondary hyperparathyroidism, your doctor should monitor your calcium levels before starting treatment with cinacalcet and during treatment with cinacalcet. You should inform your doctor if you experience any of the signs of low calcium levels as described above.

It is important that you take your dose of cinacalcet as advised by your doctor.

Note:

For children who require doses lower than 30 mg, or who are unable to swallow tablets, other dosage-strengths/pharmaceutical forms of cinacalcet are available.

Other medicines and Cinacalcet film-coated tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines particularly etelcalcetide or any other medicines that lower the level of calcium in your blood.

You should not receive Cinacalcet film-coated tablets together with etelcalcetide.

Tell your doctor if you are taking the following medicines.

Medicines such as these can affect how Cinacalcet film-coated tablets work:

- medicines used to treat **skin and fungal infections** (ketoconazole, itraconazole and voriconazole)
- medicines used to treat **bacterial infections** (telithromycin, rifampicin and ciprofloxacin)
- a medicine used to treat **HIV infection and AIDS** (ritonavir)
- a medicine used to treat **depression** (fluvoxamine)

Cinacalcet film-coated tablets may affect how medicines such as the following work:

- medicines used to treat **depression** (amitriptyline, desipramine, nortriptyline and clomipramine)
- a medicine used to relieve **cough** (dextromethorphan)
- medicines used to treat **changes in heart rate** (flecainide and propafenone)
- a medicine used to treat **high blood pressure** (metoprolol)

Cinacalcet film-coated tablets with food and drink

This medicine should be taken with or shortly after food.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Cinacalcet film-coated tablets have not been tested in pregnant women. In case of pregnancy, your doctor may decide to modify your treatment, as this medicine might harm the unborn baby.

It is not known whether cinacalcet is excreted in human milk. Your doctor will discuss with you if you should discontinue either breast-feeding or treatment with this medicine.

Driving and using machines

Dizziness and seizures have been reported by patients taking cinacalcet. If you experience these side effects, do not drive or operate machines.

Cinacalcet film-coated tablets contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.



3. How to take Cinacalcet film-coated tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will tell you how many Cinacalcet film-coated tablets you must take.

Dosage

Your doctor will take regular blood samples during treatment to monitor your progress and will adjust your dose if necessary.

If you are being treated for secondary hyperparathyroidism

The recommended starting dose for this medicine in adults is 30 mg once per day.

The recommended starting dose of cinacalcet for children aged 3 years to less than 18 years of age is no more than 0.20 mg/kg of body weight daily.

Note:

For children who require doses lower than 30 mg, or who are unable to swallow tablets, other dosage-strengths/pharmaceutical forms of cinacalcet are available.

If you are being treated for parathyroid cancer or primary hyperparathyroidism

The recommended starting dose for this medicine in adults is 30 mg twice per day.

Method of administration

This medicine must be taken orally, with or shortly after food. The tablets must be taken whole and are not to be chewed, crushed or divided. The score line is not intended for breaking the tablet.

If you take more Cinacalcet film-coated tablets than you should

If you take more of this medicine than you should you must contact your doctor immediately. Possible signs of overdose include numbness or tingling around the mouth, muscle aches or cramps and seizures.

If you forget to take Cinacalcet film-coated tablets

Do not take a double dose to make up for a forgotten dose.

If you have forgotten a dose of this medicine, you should take your next dose as normal.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Please tell your doctor immediately if you:

- start to get numbness or tingling around the mouth, muscle aches or cramps and seizures. These may be signs that your calcium levels are too low (hypocalcaemia)
- experience swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema)

Very common: may affect more than 1 in 10 people

- nausea and vomiting, these side effects are normally quite mild and do not last for long

Common: may affect up to 1 in 10 people

- dizziness
- numbness or tingling sensation (paraesthesia)
- loss (anorexia) or decrease of appetite
- muscle pain (myalgia)
- weakness (asthenia)
- rash
- reduced testosterone levels
- high potassium levels in the blood (hyperkalaemia)
- allergic reactions (hypersensitivity)
- headache
- seizures (convulsions or fits)
- low blood pressure (hypotension)
- upper respiratory infection
- breathing difficulties (dyspnoea)
- cough
- indigestion (dyspepsia)
- diarrhoea
- abdominal pain, upper abdominal pain
- constipation
- muscle spasms
- back pain
- low calcium levels in the blood (hypocalcaemia)

Not known: frequency cannot be estimated from available data

- hives (urticaria)
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema)
- unusually fast or pounding heart beat which may be associated with low levels of calcium in your blood (QT prolongation and ventricular arrhythmia secondary to hypocalcaemia)

After taking cinacalcet a very small number of patients with heart failure had worsening of their condition and/or low blood pressure (hypotension).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cinacalcet film-coated tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after "EXP". The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from humidity.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Cinacalcet film-coated tablets contain

The active substance of Cinacalcet film-coated tablets is cinacalcet (as hydrochloride).

Cinacalcet 30mg film-coated tablets

Each film-coated tablet contains 30 mg cinacalcet (as hydrochloride).

Cinacalcet 60mg film-coated tablets

Each film-coated tablet contains 60 mg cinacalcet (as hydrochloride).

Cinacalcet 90mg film-coated tablets

Each film-coated tablet contains 90 mg cinacalcet (as hydrochloride).

The other ingredients are

Tablet core:

Microcrystalline cellulose, maltodextrin, silica (colloidal anhydrous), crospovidone, sodium starch glycolate, magnesium stearate

Tablet coat:

Hypromellose, titanium dioxide E171, triacetin, iron oxide yellow E172, indigotine aluminium lake E132

What Cinacalcet film-coated tablets look like and contents of the pack

Cinacalcet 30mg film-coated tablets

Green, oval, biconvex film-coated tablets.

Cinacalcet 60mg film-coated tablets

Green, oval, biconvex film-coated tablets with an embossed line on one side.

Cinacalcet 90mg film-coated tablets

Green, oval, biconvex film-coated tablets.

They are available in blister packs of PVC/PCTFE/PVC//Al.

Cinacalcet film-coated tablets are available in packs of:

Cinacalcet 30mg film-coated tablets

28, 30, 50 and 84 film-coated tablets or 28x1, 30x1, 50x1 and 84x1 film-coated tablets (unit dose)

Cinacalcet 60mg & 90mg film-coated tablets

28, 30 and 84 or 28x1, 30x1 and 84x1 film-coated tablets (unit dose) film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

STADA, Linthwaite, Huddersfield, HD7 5QH, UK

Manufacturer

STADA Arzneimittel AG, Stadastraße 2 -18, 61118 Bad Vilbel, Germany

This leaflet was last revised in October 2019.

STADA

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